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BARD ENDOSCOPIC TECHNOLOGIES
C.R. Bard, Inc.
129 Concord Road
P.O. Box 7031
Billerica, MA 01821-7031
978-663-8989

BARD

VI 510(k) SUMMARY SAFETY AND EFFECTIVENESS INFORMATION

As required by the Safe Medical Devices Act of 1990, codified under Section 513, Part (i)(3)(A) of the Food Drug and Cosmetic Act, a summary of the safety and effectiveness information upon which substantial equivalence determination is based follows.

A. Submitter Information

Submitter's Name:	Bard Endoscopic Technologies C.R. Bard, Inc.
Address:	129 Concord Road, Bldg. #3 Billerica, MA 01821
Phone:	(978) 262 – 4868
Fax:	(978) 262 – 4878
Contact Person:	Michael A. Patz
Date of Preparation:	September 29, 2003

B. Device Name

Trade Name:	Bard® UltraView™ Multiple Band Ligator
Common/Usual Name: Classification Name:	Ligator, Esophageal

C. Predicate Device Name(s)

Trade Name:	Bard® UltraView™ Multiple Band Ligator

D. Device Description:

The Bard® UltraView™ Multiple Band Ligator is comprised of a ligating unit that fits over the distal end of an endoscope with seven premounted rubber latex ligating bands.

The ligating unit is attached to the handle by the activating sheath. The bands are 1.9 mm thick with a 5.1 mm outer diameter and a 2.0 mm diameter.

Four endoscope adapters and a centering sleeve are provided to allow the ligating unit to fit securely on endoscopes ranging from 8.5 mm to 11.5 mm. The small adapter fits 8.5 to 9.3 mm scopes. The medium adapter fits 9.3 to 10.2 mm scopes. The large adapter fits 10.2 to 10.8 mm scopes. The X-large adapter fits 10.8 to 11.5 mm scopes. A scope gauge is included to determine the required adapter for the endoscope.

E. Intended Use:

The Bard® UltraView™ Multiple Band Ligator is used for endoscopic ligation of esophageal varices.

F. Technological Characteristics Summary:

The modified Bard UltraView ligator is comprised of similar medical grade plastics, stainless steels as the predicate and uses the identical band material.

The modified design differs from the predicate device in that the ligating tip has been modified to improve the sealing integrity of the lip seal during aspiration and to improve the smooth actuation of the Band Driver over the Band Carrier by the addition of 12 ribs to the Band Driver. The sheath attaches to the handle assembly, which can be held in the physician's hand or attached to the endoscope sheath outside of the patient. The bands are deployed by depressing the thumb paddle on the handle assembly causing the bands to be pushed/deployed off of the band carrier. The modified device mounts flush with the tip of the endoscope, as does the predicate device, to allow maximum visualization. The modified and current device tips extend beyond the distal tip of the endoscope allowing variceal tissue to be suctioned into the band carrier cylinder for ligation.

G. Performance Data

Biocompatibility tests were not completed as all material changes made were to non-patient contacting components except for the color coded scope adaptors. Results of cytotoxicity testing of the colored scope adaptors showed no evidence of toxicity. Functionality testing, tensile testing and aspiration testing have demonstrated that the modified Bard® UltraView™ Multiple-Band Ligator is substantially equivalent to the current Bard® UltraView™ Multiple-Band Ligator and that the device is safe for its intended use and patient population.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 6 2003

Mr. Michael A. Patz
Regulatory Affairs Specialist
Bard Endoscopic Technologies
C. R. Bard, Inc.
129 Concord Road
P.O. Box 7031
BILLERICA MA 01821-7031

Re: K033245
Trade/Device Name: Bard® UltraView™ Multiple Band Ligator
Regulation Number: 21 CFR §876.4400
Regulation Name: Hemorrhoidal ligator
Regulatory Class: II
Product Code: 78 MND
Dated: October 6, 2003
Received: October 7, 2003

Dear Mr. Patz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K033245

Indications for Use Statement

510(k) Number (if known): ~~TBD~~ K033245

Device Name: Bard® UltraView™ Multiple Band Ligator

Indications For Use: The Bard® UltraView™ Multiple Band Ligator is used for endoscopic ligation of esophageal varices.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter Use ____ (Optional Format 1-2-96)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033245